REMARKS

By this amendment, claims 1-7 and 9-11 remain pending in this application. Claims 8 and 12 have been canceled. Claims 7 and 9-10 have been amended. No new matter is added. Applicants reserved the right to pursue the original claims in this application and in others. Applicants respectfully request reexamination in view of the above amendments and the following remarks.

On page 2 of the Office Action, claims 1-12 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully disagree.

In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms that correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein that must be relied on for enabling support. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). In other words, the Examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure. In particular, the Examiner must explain why he doubts the truth or accuracy of any statement in a supporting disclosure and to back up his assertions with acceptable evidence or reasoning that is inconsistent with the contested statement.

Apparently, the Examiner contends that the Applicants have not provided a written description "in regards to a process of determining the biological activity of the mentioned peptide" and "for an assay that a person of skill in the art could use to test the activity of the mentioned biologically active substance," and, therefore, that the Applicants have not fulfilled their requirements under 35 U.S.C. §112, first paragraph. However, as discussed above, the Examiner must first show reasonable evidence why the Applicants assertions are not true or accurate. It is not enough to show, or contend, that the Applicants have not proven biological activity. But, rather, the Examiner must show some evidence that there is no biological

activity. Here, the Office Action is completely void of any evidence or rationale why the claimed subject matter would not be biologically active. Accordingly, Applicants submit that the Examiner has not met his burden of showing non-enablement in the claims. Hence, the rejections of these claims are not proper and Applicants request removal of the same.

In page 3 of the Office Action, claims 1-12 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In particular, in claims 1, and 9-10, the feature of CT-AA is being required to be "spelled out in the first instance." Similarly, in claim 2, FMOC is being required to be "spelled out in the first instance." Also, in claim 8, T-20 and T-1249 is being required to be "spelled out in the first instance." Lastly, claim 12 is rejected because the feature of a "low void space" is allegedly indefinite.

In response, Applicants have amended the specification to define CT-AA and FMOC for the Examiner. Namely, "CT-AA" is defined as chlorotrityl group loaded with an amino acid. Also, FMOC is defined as a 9-fluorenyl-methoxy-carbonyl protecting group for protecting the alpha amine group of an amino acid. Accordingly, Applicants submit that the rejection of claims 1, 2 and 9-10 have been overcome and respectfully request the Examiner for the withdrawal of the same. Claims 8 and 12 have been canceled and the rejections as to these claims are now rendered moot.

In page 4 of the Office Action, claims 1-3, 5-6 and 9-12 are rejected under 35 U.S.C. §102(b) as being anticipated by Webber et al. (U. S. Patent No. 5,198,531). In page 4 of the Office Action, claims 1, 3 and 4 are rejected under 35 U.S.C. §102(b) as being anticipated by Ede et al. (U. S. Patent Application Pub. 2002/0076835). In page 4 of the Office Action, claims 7 and 8 are rejected under 35 U.S.C. §102(b) as being anticipated by Kang et al. (U. S. Patent No. 6,015,881). In page 5 of the Office Action, claims 7 and 8 are rejected under 35 U.S.C. §102(b) as being anticipated by Bray et al. (U. S. Patent No. 6,469,136). Applicants respectfully disagree.

The process of claim 1 requires, at least, the step of:

> "reacting an activated amino acid or activated amino acid derivative with a substituted or unsubstituted trityl alcohol resin to obtain a resin-CT-AA product. . ."

In other words, the process of claim 1 requires the step of reacting an activated amino acid or activated amino acid derivative with a substituted or unsubstituted trityl *alcohol* resin to obtain a resin-CT-AA product. The biologically active substance or agent is free of a chlorotrityl *chloride* linker-resin.

In contrast to the present invention, the disclosure of Webber concerns a substance made from a 2' chlorotrityl chloride resin (CTC). Although Webber indicates that a chlortrityl alcohol resin can be used for peptide synthesis, Webber specifically indicates that the alcohol functional group "must be converted to a chloride prior to loading" (See col. 5, lines 40-44). Accordingly, the substance of Webber is nothing more than what is disclosed in the Applicants' specification as known prior art (See Applicants' specification on pages 1-2). CTC is very difficult to make, moisture sensitive and decomposes over time. The present invention utilizes substituted or unsubstituted alcohol resins, as recited in claim 1. Accordingly, the disclosure of Webber cannot teach the process of claim 1. Hence, Applicants submit that the rejection as to claim 1 is now overcome and respectfully request the Examiner for withdrawal of the same.

Similarly, claim 9 recites, a process for making a substrate used to create a biologically active substance or therapeutic, comprising at least the step of, "reacting an activated amino acid or derivative thereof with a substituted or unsubstituted trityl alcohol resin. . ." Accordingly, claim 9 should be allowable for at least the reasons as provided above for claim 1. Additionally, claims 2-6 and 10-11 depend from claims 1 and 9, respectively, and should be allowable along with these claims and for its own unique combination of features that are not taught or suggested by the cited prior art.

Also, in contrast to the present invention, the disclosure of Ede concerns a grafted polyolefin backbone for use in chemical synthesis. Nowhere in Ede is there any discussion of reacting an activated amino acid or derivative thereof with a substituted or unsubstituted trityl alcohol resin, as required by claim 1. Although, Example 19 of Ede is entitled, "synthesis of 2-chlorotrityl alcohol lanterns," the method that follows would not produce a trityl based linker. In fact, Example 19 would produce a reduced benzophenone or diphenyl alcohol that is very different from the substance that is produced by the process of claim 1. Accordingly, the disclosure of Ede cannot teach the process of claim 1. Hence, Applicants submit that the

rejection as to claim 1 is now overcome and respectfully request the Examiner for withdrawal of the same. Additionally, claims 3 and 4 depend from claim 1 and should be allowable along with this claim and for its own unique combination of features that are neither taught or suggested by the cited prior art.

Similarly, the disclosures of Kang and Bray both concern a method for peptide synthesis of T-20 and T-1249, respectively, but nowhere in Kang or Bray are there any discussions of forming a product that is produced by the reaction of an activated amino acid or derivative thereof with a substituted or unsubstituted trityl alcohol resin, as required by claim 7. In contrast, the peptides of Kang and Bray are both formed by chlorotrityl chloride resins (See Sections 6.1 to 6.3 of Kang and col. 7, lines 29-45 of Bray). Accordingly, the peptides of Kang and Bray are nothing more than what is disclosed in the Applicants' specification as known prior art (See Applicants' specification on pages 1-2). Accordingly, the disclosures of Kang and Bray cannot teach the product of claim 7. Hence, Applicants submit that the rejections as to claim 7 are now overcome and respectfully request the Examiner for withdrawal of the same. Regarding the rejections of claim 8, Applicants note, as discussed above, that this claim is now canceled and the rejections as to this claim is now rendered moot.

In page 6 of the Office Action, claims 7-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 14-22 and 46 of co-pending U. S. Patent Application no. 10/786532 ('532 application). Applicants respectfully disagree. Claims 7 and 8 of the present application concerns the synthesis of materials using a substituted or unsubstituted trityl alcohol resin. Hence, the present application concern the use of a specific linker on a resin. Claims 14-22 and 46 of the '532 application concern the synthesis of T20 or T1249 fragments of a resin with low void space. The low void space is a property of the resin and is independent of the linker functionality. Accordingly, Applicants submit that claim 7 is patentably distinguishable from claims 14-22 and 46 of the '532 application for, at least, the reasons as discussed above. Hence, Applicants submit that the rejection is not overcome and respectfully request the Examiner for withdrawal of the same.

In view of the foregoing, Applicants submit that each of the presently pending claims are now in immediate condition for allowance and respectfully request the Examiner for allowance of the claims and to pass this application to issue. Please charge any fees due with the filing of this paper to Deposit Account No. 18-1850. If the Examiner has any questions, please feel free to contact the below referenced Attorney.

Respectfully submitted,

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Date

Edwin Oh
Attorney for Applicant(s)
Reg. No. 45,319

Edwin Oh
Patent Attorney
1105 North Market Street
Suite 1300
Wilmington, DE 19899
Tel. 302-283-2137